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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,900	02/14/2002	David B. Weiner	UPAP-0497	3962

34137 7590 12/05/2003

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EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,900	WEINER ET AL.	
	Examin r	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 9/3/03 .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 15-26 and 39-80 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 15-26 and 39-80 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 14 February 2002 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election of species drawn to an HIV antigen epitope gp160 submitted 9/3/03 is acknowledged. Claims 1-14, 27-38 have been canceled. Claims 39-80 are newly added. Claims 15-26 and 39-80 are now pending in the application, and read on the elected species, i.e. inducing immune response to HIV gp160 antigen via topical or lavage administration of a nucleotide sequence encoding the antigen. Claims 15-26 and 39-80 are under current examination.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim Objections

Claim 15 is objected to because of the claim recitation, "an infection agent" should be "an infectious agent". Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-26, and 39-80 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, and 7 of U.S. Patent No. 6,348,449.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they each drawn to a method comprising administering by topical or lavage administration to mucosal tissue of an individual a nucleic acid molecule, free of an infectious agent, encoding an antigen operably linked to regulatory sequences, wherein the mucosal tissue is selected from the group consisting of rectal, vaginal, urethral, sublingual and buccal, wherein the composition also comprising bupivacaine.

The conflicting claims differ in that claims of the cited patent do not specify that the antigen is a pathogen, a viral antigen, and preferably an HIV-gp160. However, these are taught in the specification of the cited patent (e.g. examples 3 & 4).

Accordingly, the claimed processes in the cited patent and the present application are obvious variants. Therefore, the inventions as claimed are co-extensive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 15-22, 24-26, 39-41, 45-47, 51, 55, 59, 60, 64, 68, 69, 73, 77 are rejected under 35 U.S.C. 102(e) as being anticipated by *Carson et al* (US 5,679,647, IDS/AK).

Carson et al teach a method of inducing an immune response in an individual against an antigen by administering a plasmid vector (a nucleic acid molecule free of an infectious agent) intranasally to mice, wherein the plasmid contains a DNA sequence encoding an influenza viral antigen operatively linked to a CMV promoter (regulatory sequence), which induced a humoral immune response (column 32, line 54 to column 33, line 14), and cellular immune response including antigen specific cytotoxic T lymphocytes (examples XII-XIV). *Carson et al* teach that the mucosal routes of

administration can be nasal, rectal, vaginal, urethra, or mouth topically (column 6, lines 21-27), and the principle is to deliver the naked DNA to areas rich in APC, such as the squamous mucosal epithelia of the buccal mucosa (column 6, lines 2-5). *Carson et al* also teach suppositors and topical preparations are suitable for mucosal administration (column 20, lines 11-19). Thus, *Carson et al* anticipate instant claims.

Claims 15-26 and 39-80 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

Claims 15-26 and 39-80 are directed to an invention not patentably distinct from claims 1-4, and 7 of commonly assigned U.S. Patent No. 6,348,449 as discussed in detail under Double Patenting Section, yet this application has a different inventive entity than that of the cited patent.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 6,348,449, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the

conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Carson et al* (US 5,679,647), in view of *Carson et al* (US 5,804,566).

Claim 23 is drawn to administering to an individual a nucleic acid molecule free of infectious agent via sublingual route. *Carson et al* teach administering a plasmid encoding a viral antigen via a mucosal route, but do not use the particularly term

"sublingual". However, *Carson et al* teach that the nucleic acid vaccine should be administered to the region rich in antigen-presenting cells, such as the squamous mucosal epithelia in the mouth (column 6, lines 2-5), which includes the area under the tongue. Moreover, in the second Carson patent, they clearly teach that sublingual injection is a well-known mucosal route for antigen delivery (column 20, line 46).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Carson et al* by simply selecting one of the art known routes of antigen administration, such as oral or sublingual for vaccination with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because in light of numerous art known mucosal delivery routes, this limitation would fall within the bounds of the optimization of administration. Thus, the claimed invention as a whole was clearly *prima facie* obvious in the absence of evidence to the contrary.

Claims 15, 16, 18, 19, 21, 22, 24, 26, 39-43, 45-49, 51-53, 55-57, 59-62, 64-66, 68-71, 73-75, 77-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Carson et al* (US 5,679,647), in view of *Wang et al* (PNAS 1993;90:4156-60).

These claims further define that the antigen is from human immunodeficiency virus, preferably comprises an epitope of gp160.

Wang et al teach administering a plasmid encoding an HIV gp160 as vaccine for HIV infection, and induced both humoral and cellular immune response via intramuscular injection. *Wang et al* do not teach the mucosal route of administration.

Carson et al teach administering via mucosal routes a plasmid encoding a viral antigen for vaccination, but do not teach that the viral antigen is an HIV antigen. However, *Carson et al* do teach the advantage of using mucosal administration over intramuscular administration, "ROUTES OF ADMINISTRATION OF NAKED POLYNUCLEOTIDES THROUGH SKIN OR MUCOSA REQUIRE A LOWER CONCENTRATION OF DNA TO PRODUCE THE SAME MAGNITUDE OF IMMUNE RESPONSE THAN DOES THE INTRAMUSCULAR ROUTE OF ADMINISTRATION", and this is particularly desirable when using the DNA introducing a foreign antigen (column 8, lines 30-44).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the methods taught by *Carson et al and Wang et al* by simply substituting the influenza antigen with the HIVgp160 with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because the mucosal route require less amount of antigen for inducing an effective immune response and it is within the knowledge of the skill to select the antigen of interest for vaccination. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

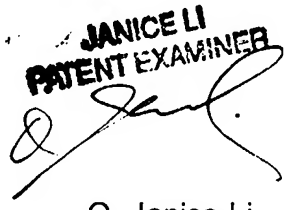
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 9:30 am - 6 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Q. Janice Li
Patent Examiner
Art Unit 1632

QL
November 10, 2003